K132614

Peregrine

Peregrine Surgical Ltd.
51 Britain Drive
New Britain, PA 18901

510 (k) Summary

August 20, 2013

Submitter: Peregrine Surgical
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New Britain, PA 18901
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NOV 14 2013

Official Correspondent: Ryan O'Leary

Trade Name: Peregrine 25ga Curved Illuminating Laser Probe

Common Name: Ophthalmic Laser Probe

Registration Number: 2529392

Classification:

	Primary
Regulation Number:	21 CFR 886.4690
Regulation Name:	Ophthalmic Photocoagulator
Class:	II
Product Code:	HQB

Device Description: Peregrine's 25ga Curved Illuminating Laser Probe is an ophthalmic light and laser delivery device. It consists of glass fiber with PVC jacket, an SMA connector, a Delrin handpiece and a needle set consisting of 304 stainless steel and nitinol. There is also an acrylic fiber with PVC jacket and an aluminum illumination connector. Both connectors plug into existing laser and light sources.

The Laser Probe can only be used in combination with a medical laser in the Vis-NIR transmission range of 532nm to 810nm with a maximum power output of 2.5 Watts and that is appropriate for photocoagulation. The light portion of the device is designed for use with the Alcon Constellation Vision System. The Constellation uses a 50 Watt Xenon arc lamp that emits light with an output of 30 lumens within the wavelength range of 400nm to 700nm.

The outer dimension of the glass fiber to be used in the proposed device is 98 microns or about .004 inches, which is about 25% of the size of the glass fiber in Peregrine's predicate device.

The acrylic fiber that will be used has an outer dimension of 254 microns or .01 inches, which is 25% of the size of the acrylic fiber used in the predicate device. The decrease in size of both fibers has created an acceptable device.

Statement of Indications for Use: For photocoagulation and illumination during ophthalmic surgery. This device delivers illumination as well as laser energy to target tissue, causing coagulation. Spot size can be varied by altering the distance between the tissue and the probe tip.

Substantial Equivalence Comparison:

Peregrine's 25ga Curved Illuminating Laser Probe is equivalent to Peregrine's Illuminated Laser Probe (PD600.10 – 510(k) #K031023) except for the curved nitinol needle, the smaller glass laser fiber and the smaller acrylic illumination fiber. Peregrine will be using smaller fibers to accommodate the smaller needle size for smaller gauge surgery. The new smaller fibers are comprised of the same materials as the larger fibers and are manufactured by the same company using the same processes.

Substantial Equivalence to: Product PD600.10 K031023 Peregrine Curved Illuminating Laser Probe	Application for 510(k): Peregrine 25ga Curved Illuminating Laser Probe Manufactured by Peregrine
Illumination and laser transmission for photocoagulation	Illumination and laser transmission for photocoagulation
Delrin®/Ni/Cu Stainless Alloy Connector	Delrin®/Ni/Cu Stainless Alloy Connector
Delrin® Handpiece	Delrin® Handpiece
Optical Fiber Glass - Silica Core .008" (200 microns)	Optical Fiber Glass - Silica Core .0030" (73 microns)
Max Threshold of Laser Fiber: 3 mW	Max Threshold of Laser Fiber: 3 mW
Transmission Range of Laser Fiber: 180 nm to 1,150 nm	Transmission Range of Laser Fiber: 180 nm to 1,150 nm
Laser Power Efficiency ≈ 95.0%	Laser Power Efficiency ≈ 94.5%
Laser Spot Size ≈ 2.45 inches	Laser Spot Size ≈ 2.4 inches
PVC Jacket (Black)	PVC Jacket (Black)
PVC Jacket - ID .040"/.070"	PVC Jacket - ID .040"/.070"
Length: 101 Inches	Length: 101 Inches
Weight: 31.6	Weight: 30.8
304 Stainless Needle	304 Sainless and Nitinol Needle
20 Gauge	25 Gauge

Acrylic Illumination Fiber - .01" OD	Acrylic Illumination Fiber -.0095" OD
Aluminum Illumination Connector	Aluminum Illumination Connector

The three aspects of performance potentially affected by the changes are light output, laser power output and laser field clarity. Peregrine performed 3 performance tests to determine substantial equivalence to Peregrine's Illuminated Laser Probe in safety and effectiveness. The results of those tests have shown that the Peregrine 25ga Curved Illuminating Laser Probe is safe and effective and substantially equivalent to the predicate device.

Nitinol, which is used in the needle set of Peregrine's 25ga Curved Illuminating Laser Probe, is used in several other FDA market-approved ophthalmic devices. Alcon's 25+ Flex-Tip Laser Probe (K062624) is one example. This shows that nitinol is an approved material to be used in ophthalmic surgical devices. Biocompatibility testing has been completed and shows %100 biocompatibility of all materials used to make this device.

The reason for using nitinol in Peregrine's 25ga Curved Illuminating Laser Probe is to allow for slight flexibility to help facilitate insertion through 25ga cannula systems. "Bend testing" was performed on both the existing and proposed design in order to evaluate safety and performance. The proposed needle set proved to be safe and effective.

The approved predicate Peregrine device and the proposed Peregrine device are both used in the same way. The devices are plugged into a laser/light source with the appropriate connectors and the laser and light are delivered to the surgical site through the applicable fibers.

This information demonstrates that Peregrine's new 25ga Curved Illuminating Laser Probe is substantially equivalent to the predicate device.

Sterilization/Shelf Life

The Device will be sterilized using ETO Sterilization. The SAL is 10 to -6.

The method used to validate the sterilization cycle is AAMI Overkill Method according to ISO 11135-1.

EO/ECH residual testing has been performed on this device and results are well below acceptable limits.

The device will not be labeled as "pyrogen free".

Packaging material will be Tyvek to Poly pouches.

Whole package integrity tests, accelerated aging and real-time aging have been performed with acceptable results for all tests.

The probes will have a shelf life of 4 years from sterilization.

Optical Radiation Safety

The Peregrine illuminating laser probe only "transmits" the laser/light energy. It does not control its intensity or power output. This is managed by the laser/light operating system to which it is attached. Glass and acrylic fiber by their nature do not change the laser or light energy/intensity. Therefore, we do not believe it is the responsibility of Peregrine to ensure adherence to ISO15752:2010 or ISO 15004-2; this is the responsibility of the laser/light source manufacturer. To ensure operational safety our probe should only be used in conjunction with laser/light sources that meet the criteria that is stated in the Instructions for Use provided with our probes.

In addition, light "transmission" is less with PD725.37SA as compared to PD600.10 which has 510(k) approval.

Biocompatibility

Biocompatibility testing was performed on the 25ga Curved Illuminating Laser Probe with nitinol tip. Test results demonstrate that all materials including nitinol, stainless steel, acrylic and glass fiber, PVC and Delrin® used to manufacture this final device are biocompatible and safe for the use in which it is intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 14, 2013

Peregrine Surgical Ltd.
% Mr. Ryan O'Leary
Product Development
51 Britain Drive
New Britain, PA 18901

Re: K132614
Trade/Device Name: Peregrine Curved Illuminating Laser Probe (PD725.37SA)
Regulation Number: 21 CFR 886.4690
Regulation Name: Ophthalmic Photocoagulator
Regulatory Class: Class II
Product Code: HQB
Dated: October 23, 2013
Received: October 25, 2013

Dear Mr. O'Leary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: Peregrine 25ga Curved Illuminating Laser Probe

Indications for Use:

For photocoagulation and illumination during ophthalmic surgery. This device delivers illumination as well as laser energy to target tissue, causing coagulation. Spot size can be varied by altering the distance between the tissue and the probe tip.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew Yang -S
2013.11.07
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K132614